

REMARKS

In reply to the Office Action mailed on August 1, 2007, Applicant submits the following remarks. Claims 1-6 and 9-20 are pending, with claims 6, 9-11, 13 and 20 being withdrawn from consideration.

The Examiner rejected claims 1-4, 12, and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,595,230 ("Suyeoka") in view of U.S. Publication No. 2003/0175323 ("Utterberg") and in further view of U.S. Publication No. 2003/0212373 ("Hall").

Claims 1-4, 12, and 18-19 cover systems that include an antimicrobial agent-bearing intervention device and a delivery tube having a perforated longitudinal partition with an opening.

Without conceding that Suyeoka could be properly construed as disclosing the other elements required by claims 1-4, 12 and 18-19, as admitted by the Examiner, Suyeoka does not disclose an antimicrobial agent-bearing intervention device. (Office Action, page 2.) Thus, Suyeoka does not disclose the systems covered by claims 1-4, 12, and 18-19. Contrary to the Examiner's assertion, however, there is no suggestion to modify Suyeoka to provide a system with an antimicrobial agent-bearing intervention device. Rather, Suyeoka discloses a catheter placement unit including a catheter shield with a catheter and a needle positioned within the catheter, where the shield has a longitudinal slot of varying width to lock the needle in place in the shield and allow freeing of the catheter from the shield and the needle. (See, e.g., Suyeoka, Abstract, col. 1, line 63-73, and Figs 1, 2, and 8.) The shield is provided to maintain the sterility of the catheter and needle assembly. (Id. col. 1, line 74- col. 2, line 4.) According to Suyeoka, the "shield enables the assembled needle and catheter to be manipulated and handled without contamination". (Id. col. 3, lines 57-60.) Thus, after reading Suyeoka, one skilled in the art would not have been motivated to modify Suyeoka to incorporate an antimicrobial agent-bearing intervention device into his device. Accordingly, one skilled in the art would not have been motivated to modify Suyeoka based on the disclosure of Utterberg in the manner suggested by the Examiner.

Further, again without conceding that Suyeoka could be properly construed as disclosing the other elements required by claims 1-4, 12 and 18-19, as admitted by the Examiner, Suyeoka does not disclose a delivery tube having a perforated longitudinal partition with an opening.

(Office Action, page 3.) Hence, for this reason also Suyeoka does not disclose the systems covered by these claims. In addition, contrary to the Examiner's position, there is no suggestion to modify Suyeoka to provide a system with a perforated longitudinal partition with an opening. Instead, Suyeoka discloses that, while his shield is flexible, it is also rigid. (See, e.g., Suyeoka, col. 1, lines 63-69 and Figs. 1 and 2). The shield includes a continuous slit with a large slot and a small slot. (Id., col. 3, lines 37-48 and Figs. 2 and 8.) The large slot can lock a needle thumb tag and thus immobilize the needle in the shield so that a catheter fin can be forced forward into the small slot in the shield to advance the catheter into the vein, after which the catheter can be released from the needle and remain in the vein. (See, e.g., id., col. 4, lines 11-42, col. 5, line 55-col. 6, line 12, and Figs. 1, 2, 7 and 8.) It is therefore apparent that the shield is rigid so that it can sustain the force used to which it is subjected under these use conditions, and the slots of varying width are specifically arranged to allow for the intended use of the device. Thus, after reading Suyeoka, one skilled in the art would not have been motivated to modify Suyeoka to replace his continuous slit and slots with a perforated longitudinal partition with an opening, at least because that person would realize that such a modification to Suyeoka's device could result in a device that did not work in the manner disclosed by Suyeoka.

Even if one skilled in the art had somehow been motivated to modify Suyeoka's device, that person would not have considered Hall, and, even if that person considered Hall, the person would not have combined Hall with Suyeoka in the manner indicated by the Examiner. Hall discloses a flexible peel-away sheath with at least one weakened area (e.g., in the form of perforations) that is not susceptible to kinking and that efficiently transfers torsional loads throughout the sheath so that the sheath pulls apart along the weakened area. (See, e.g., Hall at Abstract, paragraphs [0049], [0051], [0054] and [0057].) Thus, while the Examiner indicated that the motivation to modify Suyeoka's device to include perforations "would have been in order to provide the shield of Suyeoka with enhanced sterility" (Office action, page 3), in fact, neither Suyeoka nor Hall indicate that perforations enhance sterility. Accordingly, one skilled in the art would not have been motivated to modify Suyeoka based on the disclosure of Hall in the manner suggested by the Examiner.

In maintaining the rejection of claims 1-4, 12 and 18-19, the Examiner stated:

[T]he motivation for the combinations is found in the knowledge generally available to one of ordinary skill in the art. (Id., at 5.)

As noted above, none of Suyeoka, Utterberg, or Hall provide such motivation. Thus, the Examiner's quoted statement is nothing more than a conclusory assertion which is used to establish the rationale for combining the references. But, the Examiner is required to provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. (MPEP §2144.03.) Hence, the Examiner has not satisfied his burden in this regard.

The Examiner further stated:

[A]pplicant has fail[ed] to present that the perforations provide an advantage, are used for a particular purpose or solve a problem. Therefore, one would expect the perforations or a slot to perform equally well. (Id., at 5.)

Given the facts of the present case, Applicants are unaware of any legal support for the Examiner's rationale. Further, Applicants note that, while the devices and methods covered by claims 1-4, 12 and 18-19 are not so limited, Applicants disclose that perforations can be used to guide the hub longitudinally, and that the longitudinal movement of the hub can result in ejection of the rod from the delivery tube without touching the rod. (See, e.g., specification, paragraph [0030].) In addition, as explained above, after reading Suyeoka, one skilled in the art would not have expected that Hall's perforations would perform equally well as Suyeoka's slots in Suyeoka's device.

In summary, there is no suggestion to combine Suyeoka, Utterberg, and Hall to provide the subject matter covered by claims 1-4, 12 and 18-19. Applicants therefore request reconsideration and withdrawal of the rejection of claims 1-4, 12, and 18-19.

The Examiner rejected claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Suyeoka in view of U.S. Patent No. 6,726,658 ("Hochman"). Claim 5 covers systems that include a delivery tube having a perforated longitudinal partition with an opening. As explained above, Suyeoka does not disclose or suggest such a system. Hochman does not cure Suyeoka's deficiencies, at least because, like Suyeoka, Hochman does not disclose or suggest a delivery tube having a perforated longitudinal partition with a hub opening. Thus, neither Suyeoka nor

Hochman, alone or in combination, discloses or suggests the subject matter covered by claim 5. There is no suggestion to combine these references to provide such subject matter, and, even if the references were combined, the result would not be the subject matter covered by claim 5. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 14-16 as being unpatentable under 35 U.S.C. § 103(a) over Suyeoka, Utterberg, Hall, and further in view of U.S. Patent No. 5,419,766 ("Chang"). Claims 14-16 cover systems including a delivery tube having a perforated longitudinal partition with a hub opening. As explained above, there is no suggestion to combine Suyeoka, Utterberg, and Hall to provide the subject matter covered by claims 14-16. Chang does not cure this deficiency. Thus, there is no suggestion to combine Suyeoka, Utterberg, Hall, and Chang to provide the subject matter covered by claims 14-16. Applicants therefore request reconsideration and withdrawal of this rejection.

The Examiner also rejected claim 17 under 35 U.S.C. § 103(a) as being unpatentable over Suyeoka. Claim 17 covers systems that include an antimicrobial agent-bearing intervention and a delivery tube having a perforated longitudinal partition with a hub opening. As explained above, Suyeoka does not disclose or suggest the subject matter covered by claim 17. Thus, Applicants request reconsideration and withdrawal of this rejection.

Applicants believe the application is in condition for allowance, which action is requested.

Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket number 01194-514001.

Respectfully submitted,

Date: October 12, 2007

/Sean P. Daley/
Sean P. Daley
Reg. No. 40,978

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906